HON'BLE SRI JUSTICE L.NARASIMHA REDDY

W. P.Nos.15195, 15731 & 15738 of 2007

Dated 23rd August 2007

Between:

Sri Nidhi Medical Education and Health Care Society.

…Petitioner

and

The Director, Drugs Control Administration,
Govt. of A.P., Hyderabad & another

…Respondents

HON'BLE SRI JUSTICE L.NARASIMHA REDDY

W. P.Nos.15195, 15731 & 15738 of 2007

COMMON ORDER:

The petitioners are societies, registered under the A.P. Societies Registration Act, or other relevant enactments. One of the activities chosen by the petitioners is to run Blood Banks, without profit motive. The establishment for running of Blood Banks, is governed by the provisions of the Drugs and Cosmetics Act, 1940 (for short "the Act") and the Rules made thereunder. Till recently, it was permissible for any agency, public or private, to establish Blood Bank, on complying with the required standards. However, with a view to curb the spread of AIDS, the Government of India had restricted the grant of licences, only to those Blood Banks that are run by the Government, or Red Cross Society. Individuals and other organizations, working with the profit motive, are eliminated from the field. Hospitals, Charitable Trusts, or Voluntary Organizations, were permitted to apply for licences, provided they are approved by the State Blood Transfusion

Council, the 2nd respondent. This is the result of the amendment of Rule 122F and 122G of the Rules, through notification dated 21.12.2005.

Consequent on the change of the norms and procedure, the petitioners and several other agencies submitted applications for renewal of the licences held for some of the existing Blood Banks. The 2nd respondent considered the applications and through proceedings dated 2.2.2007, refused to accord approval for many. However, it issued No-objection certificate for some of the applicants. These proceedings are challenged by filing W.P.No.3798 of 2007 and batch. The said writ petitions were disposed of, through a common judgment dated 1.5.2007. The 2nd respondent was directed to pass orders on the applications filed by the petitioners therein, for grant of approval, duly assigning reasons separately, for each application. The exercise was directed to be completed, within a period of six weeks. The Director, Drug Control Administration, the 1st respondent, was prevented from taking any punitive steps, pending such exercise.

The 2nd respondent passed individual orders, dated 2.7.2007, rejecting the applications of the petitioners herein. The reasons mentioned in the impugned letters were that the applicants were private blood banks, and renewal of licence of an existing blood bank, is impermissible under Rule 122G of the Rules, in relation to a blood bank established by a different agency, and that any voluntary organization intending to start blood bank, must apply for approval, afresh. The petitioners challenge the orders of the rejection.

On behalf of 2nd respondent, a detailed counter affidavit is filed. It is stated that the very purpose of amending the rules is to discourage

and prohibit establishment and operation of blood banks by private agencies. It is also urged that except that the petitioners have come forward with a fresh name, the whole set up and activity continued to be the same.

Sri S.Srinivas Reddy, learned counsel for the petitioners, submits that even under the amended rules, it is permissible for the societies to run blood banks, and simply because an existing blood bank was taken over by a newly formed society, the 2nd respondent cannot refuse approval. He further contends that the 2nd respondent ought to have focused upon the compliance with the conditions by the blood banks, than on hyper-technicalities.

Dr.K.Laxminarsimha, learned Standing Counsel for the 2nd respondent, on the other hand, submits that when the petitioners' societies have come into existence, in the recent past, they have to file fresh applications, seeking approval. He contends that grant of renewal of a licence of an existing blood bank, in favour of a third party, would be a contradiction in terms.

The Government of India took note of the gravity of the situation that developed, on account of indiscriminate activity in collection and transfusion of blood by private agencies, resulting in rapid spread of AIDS. Therefore, it amended the rules, providing for establishment of blood banks only by Government and Red Cross Societies. Private individuals and organizations with profit motive, were totally discarded from the field. Hospitals, Charitable Trusts and Voluntary Organizations were permitted to apply for licences, after obtaining approval from the 2nd respondent.

The petitioners claim to be the Voluntary Associations, intending

to undertake supply of blood, without profit motive. Had it been a case where the petitioners intended to establish blood banks by themselves, there would not have been any difficulty. On an application being made to it, the 2nd respondent was expected to examine the same, with reference to the required standards, and satisfy itself as to the credibility of the applicant. If an approval is accorded, the petitioners are entitled to apply for licences. The applications submitted by the petitioners to the 2nd respondent are not for fresh licences. In fact, they were for renewal of the licences issued to the existing blood banks. If it became impermissible for an existing blood bank to get its licence renewed, mere take over of the same by the agencies, such as the petitioners, cannot pave the way for that. The parameters for grant of licences, on the one hand, and renewal thereof, on the other hand, are different. The rules do not permit of take over of an existing blood bank, which was established by an individual, or by a society.

It is no doubt true that there was some uncertainty, as to the procedure to be followed by the 2nd respondent, when the petitioners made the applications, in the beginning. In the recent past, forms were prescribed, and the petitioners have to submit fresh applications through the forms, that too, seeking approval. They cannot seek renewal of an existing licence.

For the foregoing reasons, the writ petitions are disposed of, leaving it open to the petitioners, to make fresh applications in the prescribed forms for approval, as provided for under the relevant provisions, and not for renewal of the licences of existing blood banks. The 2nd respondent shall consider the same and pass appropriate orders, within a period of three weeks, from the date of receipt of the applications. There shall be no order as to costs.

(L.NARASIMHA REDDY, J)

Dt: 23rd August 2007.
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